IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Inventor:	Tara Nylese	)	Group Art Unit: 1641
		)	
Serial No.:	10/530,464	)	Examiner: Jacqueline A. Diramo
		)	
Filed:	04/05/2005	)	Confirmation No. 4794

Title: PORTABLE DIAGNOSTIC DEVICE AND METHOD FOR DETERMINING TERMPORAL VARIATIONS IN CONCENTRATIONS

Board of Patent Appeals and Interferences
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

APPELLANT'S SECOND APPEAL BRIEF FILED UNDER 37 CFR 41.37

Sir:

This brief is in furtherance of the Notice of Appeal filed April 14, 2008 and in response to the final rejection in this application mailed on January 15, 2008.

Please proceed to the following page.

1. REAL PARTY IN INTEREST - 37 CFR 41.37(c)(1)(i)

The real party in interest in this Appeal is the Tara Nylese.

2. RELATED APPEALS AND INTERFERENCES - 37 CFR 41.37(c)(1)(ii)

There is no other appeal, interference or judicial proceeding that is related to or that will directly affect, or that will be directly affected by, or that will have a bearing on the Board's decision in this Appeal.

3. STATUS OF CLAIMS - 37 CFR 41.37(c)(1)(iii)

Claims 1, 10-21 and 25-29 are pending in the application. All of the claims have been finally rejected and are the subject of this appeal. A copy of the claims is attached hereto in the Claims Appendix. Appellant respectfully appeals the final rejection of claims 1, 10-21 and 25-29 as presented in the Final Office Action mailed 15 January 2008.

4. STATUS OF AMENDMENTS - 37 CFR 41.37(c)(1)(iv)

This application was the subject of an appeal filed 1 May 2007 from a final rejection mailed on 22 September 2007. Subsequently the Examiner withdrew the application from appeal and issued new, non-final rejections with respect to claim 1. One amendment, responsive to the non-final rejection, was filed 31 October 2007. This resulted in withdrawal of the non-final rejection of claim 1. However, a second final office action, mailed 15 January 2008, presents new grounds of rejection. No amendment has been filed to overcome the rejections presented in The second final office action mailed 15 January 2008. Thus the claims stand rejected based on the art rejections and reasons presented in the Final Office Action mailed15 January 2008.

5. SUMMARY OF THE CLAIMED SUBJECT MATTER- 37 CFR 41.37(c)(1)(v)

5A. BRIEF BACKGROUND PROVIDING CONTEXT FOR THE SUMMARY OF CLAIMED SUBJECT MATTER

Tracking of variable chemical concentrations in fluids is key to monitoring health, medical and environmental conditions. Most conventionally, this information has been used to monitor conditions at a given point of time. However, in some contexts, it is beneficial to use this information to identify deleterious trends, enabling prompt awareness which is often essential for timely intervention. For some conditions, such as determining whether blood-alcohol levels have exceeded a threshold relating to safe use of a motor vehicle, the monitoring can be limited to performing one or more rapid tests, i.e., wherein the an individual test result is determinatve of an unsafe condition without reference to other test results.

For other conditions, such monitoring has required complex, laboratory-based assay methodologies wherein results of a second test must be compared to results of a first test to identify a trend. Yet it is desirable to provide faster and more simplified analysis procedures in order that changes in chemical concentrations, such as hormone levels, can be more conveniently and quickly assessed.

By way of example, it is common to assess the health of a pregnancy during the first trimester by quantitatively assessing changes in blood level concentration of chorionic gonadotrophin (hCG). Typically, hCG levels will double every two to three days for a normal pregnancy while absence of a consistent increase may be suggestive of a miscarriage or an ectopic pregnancy. The only generally accepted method of monitoring hCG levels on multiple occasions, e.g., one to two days apart, has been through performance of quantitative laboratory tests, requiring that patients make multiple visits to have blood drawn. Such quantitative tests cannot be performed in a home environment and there is usually a delay of at least 24 hours before each set of results becomes available. There is a need to provide rapid and reliable screening tests for assessing conditions, including but not limited to the health of a pregnancy.

5B. CONCISE EXPLANATION OF SUBJECT MATTER DEFINED IN EACH INDEPENDENT CLAIM

The following summary references exemplary embodiments described in the Specification and which are covered by specific claims, but it is to be understood that the claims are not so limited in scope.

According to **independent claim 1**, a method for determining, between two times, a change in a level of concentration of an analyte present in a source (*see page 19, lines 17-18*) includes

(i) providing multiple unitary test devices (See devices 210 of the kit 200 shown in FIGS 10 and 11 as well as page 18, lines 12-27), each unitary test device (210) including a plurality of regions (See membranes 42 of FIGS 2 and 7 and page 11, lines 9-13, page 16, lines 14-19), each region responsive at a different sensitivity level (See page 11, lines 9-13) to indicate presence of the analyte in the source (See page 19, lines 30- page 20, line 2);

(ii) bringing a first sample from the source into contact with a first of the unitary test devices (*210*) at a first time to induce, at the first time, a visually observable response in one or more regions (*42*) of the first test device based on the source containing a minimum level of analyte concentration (*See page 20, lines 2 – 4*);

(iii) subsequently bringing a second and different sample from the same source into contact with a second of the unitary test devices at a second time to induce at the second time a visually observable response in one or more regions (*42*) of the second test device based on the source containing a minimum level of analyte concentration; (*See page 20, lines 5 - 8*) and

(iv) comparing a visually observable response induced in the first test device at the first time directly with a visually observable response induced in the second test device at the second time to provide information about a change in the level of analyte concentration between the two times (*See page 20, lines 2-21*).

According to **independent claim 10**, a method for monitoring changes in analyte level of a source includes:

(i) defining multiple measurably distinguishable sensitivity levels each indicative of a different amount of analyte in the source (*See page 5, lines 1-3*);

(ii) providing first and second test units (*210, See Figure 10*),

the first test unit (*210*) including a first region (*42a*) responsive to the presence of analyte in the source at a first of the sensitivity levels (*44a*; *See page 5, lines 3-5, and page 11, lines 20-27*);

the second test unit (*210*) including a first region thereon responsive to the presence of analyte in the source at a second of the sensitivity levels (*44b; See page 5, lines 5-6, and page 11, lines 20-27*);

(iii) providing a first sample from the source at a first time (*See page 5, lines 6-9*);

(iv) bringing the first sample into contact with the first unit (*210*) to allow the first region 42a to provide an indication (*44a*) as to whether analyte is present in the sample at at least the first level (*See page 5, lines 6-9*);

(v) providing a second sample from the source at a second time subsequent to providing the first sample (*See page 5, lines 9-11*); and

(vi) bringing the second sample into contact with the second unit (*210*) to allow the first region (*42a*) to provide an indication (*44b*) as to whether analyte is present in the second sample at at least the second level (*See page 5, lines 9-11*),

wherein indications of presence of analyte in the first sample and indications of presence of analyte in the second sample provide evidence as to whether there has been a change in analyte level between the first time and the second time.

According to **independent claim 20**, a method for monitoring changes in analyte level of a source, includes:

(i) providing two or more test units (*210, see FIG 10*) each including multiple regions (*42a, 42b, 42c, 42d*) thereon, each region in each unit responsive to the presence of an analyte in the source at a sensitivity level measurably distinguishable (*44a, 44b, 44c or 44d*) from another region (*44a, 44b, 44c or 44d*) in the same test unit (*See page 4, lines 7-9*);

(ii) bringing a first sample from the source into contact with a first of the units (*210*) to allow one or more of the regions (*42*) thereon to indicate whether the analyte is present in the sample at at least one of the levels (*44, see page 4, lines 9-12*); and

(iii) on an occasion subsequent to providing the first sample, bringing a second sample from the source into contact with a second of the units (*210*) to allow one or more of the regions (*42*) thereon to indicate whether the analyte is present in the second sample at at least one of the levels (*44, see page 4, lines 12-15*),

wherein different indications of presence of analyte in the first and second samples provide evidence as to whether there has been a change in analyte level subsequent to providing the first sample.

According to **independent claim 25**, a method for determining a change in a level of concentration of an analyte present in a source (*see page 19, lines 17-18*) includes:

(i) providing multiple unitary test devices (See devices 210 of the kit 200 shown in FIGS 10 and 11 as well as page 18, lines 12-27), each unitary test device (210) including a plurality of regions (See membranes 42 of FIGS 2 and 7 and page 11, lines 9-13, page 16, lines 14-19), each region responsive at a different sensitivity level (See page 11, lines 9-13), each region responsive at a different sensitivity level (See page 11, lines 9-13) to indicate presence of the analyte in the source (See page 19, lines 30- page 20, line 2) without being determinative of a numerical concentration of the analyte in the source;

(ii) on a first occasion, bringing a sample from the source into contact with a first of the unitary test devices (*210*) to induce a visually observable response thereto in one or more regions (*42*) of the first test device when the source contains a predetermined minimum level of analyte concentration (*See page 20, lines 2 – 4*);

(iii) subsequently, on a second occasion, bringing a different sample from the same source into contact with a second of the unitary test devices (*210*) to induce a visually observable response thereto in one or more regions (*42*) of the second unitary test device when the source contains a predetermined minimum level of analyte concentration (*See page 20, lines 5-8*); and

comparing a visually observable response induced in the first test device directly with a visually observable response induced in the second test device to provide information about a change in the level of analyte concentration without requiring determination of analyte concentration in the source on either occasion (*See page 20, lines 2 – 21*).

6. GROUNDS OF REJECTION TO BE REVIEWED UPON APPEAL - 37 CFR 41.37(c)(1)(vi)

Claims 1, 20, 21, 25 and 29 have been rejected under 35 U.S.C. Section 102 as being anticipated by Toranto et al. (US 2003/0175992).

Claims 10 – 16, 19 and 28 have been rejected under 35 U.S.C. Section 103(a) as being unpatentable over Boehringer et al. (WO98/39657) in view of Toranto et al. (US 2003/0175992).

Claims 17 and 18 have been rejected under 35 U.S.C. Section 103(a) as being unpatentable over Boehringer et al. (WO98/39657) in view of Toranto et al. (US 2003/0175992), as applied to claims 10 and 16, and in further view of Cole (U.S. 6,656,745).

Claims 26 and 27 have been rejected under 35 U.S.C. Section 103(a) as being unpatentable over Toranto et al. (US 2003/0175992) in view of O'Connor et al. (US 2003/0124737).

7. ARGUMENT 37 CFR 41.37(c)(1)(vii)

Overview of Argument

In the following argument, it is demonstrated that each of the rejections under section 102 or under Section 103 is deficient because none of these claims can be read upon either the Toranto reference, or the Boehringer reference in view of the Toranto reference, or any of the foregoing in further view of Cole or O'Connor. To facilitate understanding of the differences between each of the independent claims 1, 20 and 25 and the Toranto reference, Section 7A includes a brief discussion concerning misapplication of the Toranto reference. Also, to facilitate understanding of the differences between independent claim 10 and the combination of the Boehringer and Toranto references, Section 7B includes a brief discussion relating to the Boehringer reference.

Patentability of Each Claim is to be Separately Considered

Appellant urges that patentability of each claim should be separately considered. All of the claims are separately argued. General argument, based on deficiencies in the rejection of independent claims 10 and 20 under Section 102 demonstrates patentability of claims 11 – 19 and 21. However, none of the rejected claims stand or fall together because each claim further defines a unique combination that patentably distinguishes over the art of record. For this reason, the Board is requested to consider each argument presented with regard to each dependent claim. Argument demonstrating patentability of each dependent claim is presented under subheadings identifying each claim by number.

7A. APPELLANTS TRAVERSE ALL REJECTIONS BASED ON THE TORANTO REFERENCE ALONE OR BASED ON THE TORANTO REFERENCE IN FURTHER VIEW OF THE O'CONNOR REFERENCE. PATENTABILITY OF EACH CLAIM SHOULD BE SEPARATELY CONSIDERED.

7A(1) ALL REJECTIONS OF THE INDEPENDENT CLAIMS 1, 20 AND 25 UNDER SECTION 102 BASED ON THE TORANTO REFERENCE ARE IN ERROR.

The Appellant traverses the rejections of claims 1, 20 and 25 under 35 USC 102(b) based on the Toranto reference. As fully argued herein, the Toranto reference fails to disclose each and every element as set forth in each of the independent claims 1, 20 and 25. This deficiency renders the rejections based on the Totanto reference under Section 102 improper.

BRIEF DISCUSSION OF THE TORANTO REFERENCE

As described in the Abstract, the Toranto reference relates to:

(i) test systems for the oral detection of analytes in saliva, and

(ii) also provides compositions and methods for storing multiple assay tests, and

(iii) also provides compositions and methods for measuring the concentration of analytes in a sample.

See, also, paragraph [0006] of Toranto. In the course of specifically describing numerous systems, compositions and methods, Toranto discloses a large number of elements which are each associated with the described embodiments. Potentially, many additional combinations not disclosed or suggested by Toranto may be formed by rearranging elements from among different embodiments. While Toranto does disclose some elements of Appellant's claimed combinations, this has no relation to criteria under Section 102. It is only the Appellant who teaches or suggests these combinations.

The following discussion illustrates that the very pieces of disclosure from the Toranto reference which were used to construct the combinations of Appellant's claims 1, 20 and 25 were reassembled from numerous different embodiments directed to different inventions. To illustrate that the Section 102 rejection is based on no more than a piecemeal reconstruction of the claimed combinations, it is first noted that the Toranto reference addresses multiple different objectives, and to meet those objectives, the reference discloses different devices in support of each.

One objective disclosed in the Toranto reference is to provide a small delivery system comprising a plurality of test assay devices (see paragraph [0019]). The delivery system of Figures 3 and 4 is exemplary of a small system approximately 2mm in thickness with overall dimensions of 5.5 cm x 8.25 cm. See paragraph [0132]. The system of Figure 2 is shown to include the device according to Figure 1. Such devices are described as ones which indicate presence of glucose or alcohol at or above a certain threshold level. See paragraph [0156] (first sentence), paragraph [0167] (first sentence), and paragraph [0168]. These embodiments are consistent with related disclosure at paragraphs [0054] – [0056] wherein a system stores multiple assay tests and an assay test comprises a single device such that the assay test is small, fast and accurate. See paragraph [0055].

With apparent reference to the delivery system of the preceding paragraph [0056], the paragraphs [0057] through [0062] discuss several embodiments of single devices suitable for use in the delivery system of Figures 3 and 4. Specifically, paragraph [0058] begins "Thus, in some embodiments the assay test ... comprises a single device so that it is easy to use." None of the disclosure in Toranto indicates use, in a delivery system, of a single assay test with more than one device or a single assay test device having multiple sample regions.

It is in this first context that paragraphs [0054] through [0057] of the reference refer to multiple assay test devices contained within a delivery system, wherein each single device is easy to use and, for example, determinative as to whether an analyte concentration is below a threshold. See, also, paragraph [0059]. It is also understood that for Toranto's embodiments of "delivery systems" the disclosed "test assay" device is "a simple strip containing a reactive site at one end, such that the reactive site provides a detection element in the presence of analyte ..." See paragraph [0066]. See also Figure 1 Such embodiments of assay test devices are known to be useful for rapid determination of alcohol detection. Paragraph [0146] indicates such a use by individuals in making decisions about whether or not to operate a motor vehicle.

Paragraph [0112] describes the embodiment of Figure 1 as "the alcohol concentration assay test of the present invention" while Figure 2 describes construction thereof (see paragraph [0113] and Figures 3 and 4 illustrate appropriate "delivery systems" with multiple assay test devices "so that individuals have enough assay tests to determine if their analyte concentration [e.g., for safe driving] has dropped over time on one distinct occasion." See paragraph [0132]. Reference to "over time on one distinct occasion" is understood to be in the context of a period over time in which a person may repeatedly measure alcohol level in order to determine when it is safe to drive a vehicle.

Many details of possible embodiments for portable and repeatable alcohol tests, e.g., a wait-and-retest-program, are described at paragraphs [0148] through [0163] of the Toronto reference. However, none of the systems or methods disclosed in the Toranto reference are of a type which require a comparison between test results from different devices in order to make a determination. Instead, for all embodiments of the Toranto reference, it appears that determinations can always be made on the basis of individual assays as to whether an analyte level is at or above a threshold level, e.g., to indicate whether alcohol or glucose concentrations

exceed a threshold level. The Toranto reference is not concerned with anything more than accumulating such discrete assay information.

In a second context, concerning quantitation, at least one embodiment in the Toranto reference (which the Examiner appears to rely upon) discloses a test assay device which has no apparent relation to the delivery system embodiments. This embodiment concerns quantitative measurement. See the penultimate sentence of paragraph [0102] which states "In some embodiments, the detectable signal is measured to determine a quantitative amount of analyte in the sample." It is stated at paragraph [0009] that in

> "some embodiments ... multiple collection sites and multiple reaction sites are used. The plurality of collection sites find use, for example, in detecting different threshold concentrations of analyte (e.g., a first collection site that detects 0.4% of analyte in saliva and a second collection site that detects 0.8% of analyte in saliva), different detectable readouts ..., different read-out formats ..., different detection purposes ... and the like."

The embodiment concerning quantitative measurement is further discussed in the context of measuring alcohol level. See paragraph [0156] in which the Toranto reference apparently discloses that a single test device may include multiple collection sites and reaction sites. In this regard, paragraph [0156] states

> "The plurality of collection sites find use, for example, in detecting different threshold concentrations of alcohol (e.g., a first collection site that detects 0.4% and a second collection site that detects 0.8%) ..."

However, the Toranto reference does not at all disclose a test device suitable for operation consistent with the methods of claims 1, 20 and 25, e.g., wherein one sample can induce observable responses in multiple regions of the device. A device suitable for the claimed methods must be capable of displaying responses in multiple regions. For example, claim 1 requires both that

a. the method be practiced with unitary test devices which each include "a plurality of regions, each region responsive at a different sensitivity level to indicate presence of the analyte in the source"

and

b. with respect to the first or second sample, that there is "a visually observable response in one or more regions of the ... test device ... "

Although paragraph [0156] of Toranto discloses an embodiment of a single device for "detecting different threshold concentrations of alcohol" such as 0.4% and 0.8%, there is simply no disclosure or suggestion for comparing information from a first sample (i.e., one single sample) in a first device having multiple regions (each region responsive to the first single sample at different sensitivity levels), with information from a second sample (i.e., another single sample) in a second device having multiple regions (each region responsive to the second single sample at different sensitivity levels). Moreover, there is no suggestion that any of Toranto's embodiments of a single device for "detecting different threshold concentrations of alcohol" such as 0.4% and 0.8%) would be incorporated into any of Toranto's embodiments of a delivery system. None of the text or figures disclose or suggest such a combination.

If the method of, for example, claim 1 did not so require that each of the plurality of regions of a device "be responsive at a different sensitivity level" to a single sample (i.e., the first or second sample) then it might be possible to read Appellant's methods on embodiments of the Toronto reference. But with each unitary device including regions each responsive at a different sensitivity level, the method of claim 1 cannot be practiced with "a simple strip containing a reactive site at one end, such that the reactive site provides a detection element in the presence of analyte ..." See again paragraph [0066] of Toranto.

A distinction between the invention of claims 1, 20 and 25 and all embodiments disclosed in the Toranto reference is whether actual use is made of data from multiple test devices wherein each device is responsive to the same one sample (first or second sample) at multiple differing sensitivity levels.

No use of such data is suggested in the Toranto reference and no suitable device for aquiring such data is described in the Toranto reference. No device disclosed in the Toranto reference is consistent with performing any of Appellant's claimed methods.

As required in claim 1, it is only the appellant who discloses the method to be practiced on a unitary device that is responsive to the same one sample (first or second sample) at different sensitivity levels. Thus Appellants require more than merely comparing visually observable responses at two times. A feature of the claims is the ability "to provide information about a change in the level of analyte concentration between the two times" based on only two samples.

Shortcomings in the Toranto reference with respect to each claim are specifically identified in the following argument, but generally, as described at paragraph [0156] the devices of Toronto are each individually capable of providing desired information without requiring any comparison between assay tests. Apparently, this is why it is satisfactory for the "preferred embodiments" among the multiple Toranto embodiments described in paragraph [0156] to provide an on/off readout if the alcohol concentration is above a certain threshold.

GENERAL BASIS TO OVERTURN ALL REJECTIONS UNDER SECTION 102

In order to sustain the rejection of independent claims 1, 20 and 25 under Section 102 it is necessary to clearly identify the particular part of the reference relied upon. As stated in 37 CFR 1.104(c)(2), when a reference is complex or shows or describes inventions other than that claimed by the applicant, the particular part of the reference relied upon must be designated as nearly as practical. Because the Toranto reference discloses multiple distinct embodiments it would be inappropriate to take a "shotgun" approach to reject a claim, i.e., by citing in the aggregate many passages as though the applicant should be responsible for rearranging the passages in order to confirm that a piecemeal reassembly might be possible.

Unfortunately this is the extent of the Examiner's basis for the rejection. At pages 3- 4 of the second final office action the rejection of claims 1, 20, 21, 25 and 29 consists of a mere recitation of Appellant's claim language followed by a serial citation of 25 paragraphs from the

Toranto reference (spanning multiple unrelated embodiments), without explanation as to how each of the 25 citations might be applied to each element of each rejected claim.

More is required, but as already shown, the Toranto reference does not contain requisite disclosure to sustain an art rejection under Section 102 or under Section 103. That is, even if it were permissible to perform a reconstruction of "pieces" extracted from different embodiments, the requisite "elements" are missing from the prior art.

The Toranto reference cannot be applied under Section 102 because it is not possible to find one embodiment in the reference which discloses all of the features claimed in even one of the independent claims 1, 20 and 25. The rejection merely lists an assembly of passages. Nor can the Toranto reference be applied under Section 103 because it is not even possible to combine pieces from different embodiments in the reference to reconstruct all of the features claimed in any one of the independent claims 1, 20 and 25.

7A(1)i REJECTION OF INDEPENDENT CLAIM 1 UNDER SECTION 102 BASED ON THE TORONTO REFERENCE IS IN ERROR.

This rejection of claim 1 is premised on disclosure of a method in the Toranto reference which determines, "between two times, a change in a level of concentration of an analyte present in a source" according to the combination including:

"providing multiple ... devices, each ... including a plurality of regions ... responsive at a different sensitivity level to indicate presence of the analyte ...

bringing a first sample ... into contact with a first of the ... devices ... to induce ... a visually observable response in one or more regions of the first test device ... and

subsequently bringing a second ... sample ... into contact with a second of the ... devices ... to induce ... a visually observable response in one or more regions of the second test device ... and

comparing a visually observable response induced in the first test device ... with a visually observable response induced in the second test device ... to provide information about a change in the level of analyte concentration ..."

However, the rejection fails to identify an embodiment in the Toranto reference which the claims can be read upon. In fact, theere is no embodiment in the Toranto reference which discloses or even suggests this combination. In order to nonetheless make a rejection of claim 1 under Section 102, the Examiner has avoided reading the claims on the Toranto reference and has only suggested that a piecemeal collection of passages from the Toranto reference would anticipate. Urging that all of the elements in the claimed combination are present in the prior art is different from anticipating the claim. More is required. More than a piecemeal assembly is also required to render a combination obvious.

One deficiency which precludes rejection of claim 1 under both Section 102 and Section 103 is that the reference does not at all disclose the requisite devices with which the method must be performed. According to claim 1 the unitary device includes:

> "a plurality of regions, each ... responsive at a different sensitivity level to indicate presence of the analyte in the source ..."

According to claim 1 it is only the first sample obtained "at the first time" which induces the response in the first device, and it is only the second sample obtained "at the second time" which induces the response in the second device. With the requirement of each **device** including a plurality of regions each responsive at a different sensitivity level, it is only the claimed method that is capable of providing,, with one sample, the visually observable response in one or more regions of the device.

The Toronto reference does not teach or suggest a method wherein the device has a plurality of regions that are "each ... responsive at a different sensitivity level" so that a first sample can induce a visually observable response ... [Emphasis Added]"

At best, the Toranto reference only discloses a device responsive at one sensitivity level for each sample. This is true for all disclosed embodiments, including the embodiments having multiple collection sites as described in the last sentence of paragraph [0009] of the Toranto reference.

In conclusion, although the rejection cites numerous passages and examples from the reference, it has been demonstrated that none of these, alone or in combination, teach or suggest the following combination of claim 1:

providing multiple unitary test devices, each ... including a plurality of regions ... each ... responsive at a different sensitivity level ...

bringing a first sample ... into contact with a first of the unitary test devices at a first time to induce, at the first time, a visually observable response in one or more regions of the first test device ... and ...

bringing a second and different sample ... into contact with a second of the unitary test devices at a second time to induce at the second time, a visually observable response in one or more regions of the second test device ...

Mere identification of a device which might be suitable as a test unit with which to monitor analyte concentration falls short of aniticipating the claimed method. For all of these reasons the rejection of claim 1 based on the Toranto reference is without support and is clearly in error. Nothing in the reference anticipates or suggests the claimed invention. It has been incumbent upon the Examiner to come forward with citations which support aniticipation or obviousness.

Appellants have done the work which should have been completed before imposing a final rejection on new grounds. The rejection under Section 102 is in error and there would be no basis to reject claim 1 under Section 103. It is therefore requested that the rejection of claim 1 under Section 102 be withdrawn and the claim should be allowed.

7A(1)ii REJECTION OF INDEPENDENT CLAIM 20 UNDER SECTION 102 BASED ON THE TORONTO REFERENCE IS IN ERROR.

This rejection of claim 20 is also premised on disclosure of a method in the Toranto reference, but this cannot be on the same basis as which claim 1 has been rejected since claim 20 differs from claim 1. However, the final rejection does not indicate which of the 25 paragraph citations in the Toranto reference are relevant to the claimed method for monitoring changes in analyte level of a source. The method requires:

> "... test units each including multiple regions thereon, each region in each unit responsive to the presence of an analyte in the source at a sensitivity level measurably

> distinguishable from another region in the same test unit;
>
> bringing a first sample ... into contact with a first of the units to allow one or more of the regions thereon to indicate whether the analyte is present in the sample at at least one of the levels; and ...
>
> bringing a second sample ... into contact with a second of the units to allow one or more of the regions thereon to indicate whether the analyte is present in the second sample at at least one of the levels,
>
> wherein different indications of the presence of analyte in the first and second samples provide evidence as to whether there has been a change in analyte level ... [Emphasis Added]."

A feature of the method of claim 20 is allowing one sample, depending on the analyte concentration therein, to induce indications in multiple regions. None of the embodiments in the Toranto reference allow one sample to induce one or multiple responses depending on the analyte concentration. It is only the Appellant who teaches allowing each of the two samples to induce multiple responses. The Toranto reference is not enabling for creating multiple responses with one sample. That is, none of the devices disclosed by that reference allow one sample to produce a response in multiple regions each corresponding to a different sensitivity level.

A second reason that the Toranto reference cannot anticipate is that there is no embodiment in the Toranto reference which can result in different indications of the presence of analyte based on bringing only one (first) sample into contact with the first unit and bringing only one (second) sample into contact with a second unit. Appellant's method for providing "different indications of presence of analyte in the first and second samples" is not found or suggested in the Toranto reference.

The rejection fails to identify any one embodiment in the Toranto reference which claim 20 can be read upon. In fact, for the above-stated reasons, there is no embodiment in the Toranto reference which discloses or even suggests this combination. In order to nonetheless make a rejection of claim 20 under Section 102, the Examiner has avoided reading the claims, element by element, on specific subject matter in the Toranto reference. Instead, it was only implied that some of the citations in a large collection of passages from the Toranto reference would form a basis for showing anticipation. The combination is not anticipated by or obvious in view of

Toranto. A prior art rejection requires more than a piecemeal re-assembly. In this case, the essential elements to recreate the claimed combination are not all present in the reference. At best, the Toranto reference only discloses a device responsive at one sensitivity level for each sample. This is true for all disclosed embodiments, including the embodiments having multiple collection sites as described in the last sentence of paragraph [0009] of the Toranto reference.

In conclusion, although the rejection cites numerous passages and examples from the reference, it has been demonstrated that none of these, alone or in combination, teach or suggest the requisite subject matter. For all of these reasons the rejection of claim 20 based on the Toranto reference is without support and is clearly in error. Nothing in the reference anticipates or suggests the claimed invention. The rejection under Section 102 is in error and there would be no basis to reject claim 20 under Section 103. It is therefore requested that the rejection of claim 20 under Section 102 be withdrawn and the claim should be allowed.

7A(1)iii REJECTION OF INDEPENDENT CLAIM 25 UNDER SECTION 102 BASED ON THE TORONTO REFERENCE IS IN ERROR

This rejection of claim 25 is also premised on disclosure of a method in the Toranto reference, but this cannot be on the same basis as which claims 1 and 20 have been rejected since claim 25 differs from the other independent claims. Again, as noted for the other claims 1 and 20, the final rejection does not indicate which of the 25 citations in the Toranto reference the Examiner would combine to anticipate the claimed method for determining a change in a level of concentration of an analyte present in a source.

The method of claim 25 is further distinguished over the Toranto reference (relative to claims 1 and 20) because it requires:

> "providing multiple unitary test devices, each unitary test device including a plurality of regions, each region responsive at a different sensitivity level to indicate presence of the analyte in the source without being determinative of a numerical concentration of the analyte in the source [Emphasis Added] ..."

None of the assay test devices of the Toranto reference can meet these requirements. Nonetheless, the rejection does not at all so much as acknowledge these requirements. In fact, at page 4 of the final rejection it is erroneously stated that the "limitations" of claim 25 are "discussed above with respect to Applicant's claim 1."

With the multiple regions of each device being responsive at a different sensitivity level, claim 25 also requires

> "bringing a sample ... to induce a visually observable response thereto in one or more regions of the first test device when the source contains a predetermined minimum level of analyte concentration ..."

The Toranto reference cannot be enabling for this subject matter because there is no disclosure or suggestion therein for a device in which "each region [is] responsive [to one sample] at a different sensitivity level" without being determinative of a numerical concentration. At best, the Toranto reference only discloses a device responsive at one sensitivity level for each sample. This is true for all disclosed embodiments, including the embodiments having multiple collection sites as described in the last sentence of paragraph [0009] of the Toranto reference.

The invention of claim 25 is distinct and non-obvious for still another reason. According to the method, the step of comparing is performed "without requiring determination of analyte concentration in the source on either occasion." The final rejection does not cite any support in the reference which would even suggest this subject matter.

In conclusion, although the rejection cites numerous passages and examples from the reference, the Examiner has failed to provide a showing. None of these passages, alone or in combination, teach or suggest the claimed combination.

Mere identification of a device which might be suitable as a test unit with which to monitor analyte concentration falls short of anticipating the method of claim 25. For all of these reasons the rejection is without support and is clearly in error. Nothing in the reference anticipates or suggests the claimed invention. The Examiner has not carried the burden of coming forward with citations which support aniticipation or obviousness. Appellant has reviewed the Toranto reference and cannot find any basis for this rejection. The rejection under Section 102 is in error. Nor is there any basis for a rejection under Section 103. It is therefore

requested that the rejection of claim 1 under Section 102 be withdrawn and the claim should be allowed.

FURTHER REBUTTAL TO THE EXAMINER'S ARGUMENTS

Previously the Examiner has also argued that the devices disclosed in the references "allow" for the claimed method. The possibility that a device of the prior art might be used to practice a novel method does not render the method anticipated. Indeed, the claimed methods may possibly be practiced with prior art devices. Yet it is well established that new methods of using known devices are patentable subject matter. So it did not follow that the references would anticipate the claims merely because they disclose devices with which a novel method can be practiced.

Now, with respect to the independent claims rejected based on the Toranto reference, it is argued by the Appellant that the Toranto reference is not enabled and does not allow for creating multiple responses with one sample. That is, none of the devices disclosed by that reference allow one sample to produce a response in multiple regions each corresponding to a different sensitivity level. This is a case wherein a new method cannot be practiced on a known device. So it follows that the Toranto reference cannot anticipate any of the independent claims 1, 20 or 25.

7A(2) THE REJECTIONS OF THE DEPENDENT CLAIMS 21 AND 29 UNDER SECTION 102 BASED ON THE TORANTO REFERENCE ARE IN ERROR.

7A(2)i THE REJECTION OF THE DEPENDENT CLAIM 21 UNDER SECTION 102 IS LACKS ADEQUATE SUPPORT.

Claim 21, which depends from claim 20 is allowable because the rejection of claim 20 under Section 102 is in error. Furthermore, claim 21 further distinguishes over the prior art by

requiring that provision of "one of the test units includes adhesively mounting the multiple regions on a substrate." None of the disclosure in the Toranto reference discloses this subject matter. The burden for establishing a basis for this rejection has not been carried. Reversal of the rejection is requested.

7A(2)ii THE REJECTION OF THE DEPENDENT CLAIM 29 UNDER SECTION 102 LACKS ADEQUATE SUPPORT.

Claim 29, which also depends from claim 20, is allowable because the rejection of claim 20 under Section 102 is in error. Furthermore, claim 21 further distinguishes over the prior art by requiring that provision of "two or more test units includes forming the test units separate and apart from one another." None of the test units of Toranto can anticipate this combination.

7B. APPELLANTS TRAVERSE ALL REJECTIONS BASED ON THE BOEHRINGER REFERENCE IN VIEW OF THE TORANTO REFERENCE ALONE OR IN FURTHER VIEW OF THE COLE REFERENCE. PATENTABILITY OF EACH CLAIM SHOULD BE SEPARATELY CONSIDERED.

7B(1) THE REJECTION OF INDEPENDENT CLAIM 10 BASED ON THE BOEHRINGER REFERENCE IN VIEW OF THE TORANTO REFERENCE IS IN ERROR.

The Appellant traverses the rejection of claims 10 under 35 USC 103(b) based on the Boehringer reference in view of the Toranto reference. As fully argued herein, the combination of the Boehringer reference and the Toranto reference fails to disclose each and every element which must be shown and thus the combination fails to meet the minimum criteria for an obviousness rejection.

BRIEF DISCUSSION OF THE BOEHRINGER REFERENCE

As described in the Summary of the Invention, the Boehringer reference discloses methods, devices and kits for visually quantifying the amount of analyte in a sample. FIGS 2 and 3 are illustrative of a single device which includes multiple test regions 16. In FIG 2, multiple separate matrices or regions each define a flow path emanating from a common sample zone. Barrier or threshold levels are set for each region to assess concentration of analyte when portions of the sample are applied among the multiple zones. See pp. 25 – 26 of the reference. In FIG 3, there is shown a "multi-flow path device" in which each flow path utilizes a different concentration of soluble antibody to facilitate creation of a different threshold response level for purposes of quantitation. See page 28. As stated at page 28, "soluble antibody concentrations and barrier zone break-through thresholds could be used to modulate the response ... of each flow path and facilitate quantitation." The text at pp 28-29 goes on to state that this is useful when concentration of analyte in a sample occurs over a wide dynamic range such that

> "at low analyte concentrations color will only appear on flow paths having low concentrations of soluble antibody ... [but] as analyte concentration increases, color will also appear on detection zones on flow paths having higher amounts of soluble antibody."

Based on these excerpts, Appellant urges that it is accurate to characterize the Boehringer reference as concerning quantitation of analyte concentration levels from a **single** source, with portions of the source being concurrently provided along each of the several flow paths so as to identify and count a number of visual responses among the multiple flow paths. Accordingly, it is possible to visually assess relative concentration of analyte in the source by observing the number of colored lines appearing on the test units in a single device. To the extent the reference uses the term sample with regard to different receiving zones it is only in the context of providing portions of the same sample in different zones, e.g., portions of the source taken on the same occasion from a single source and applied concurrently along multiple flow paths to observe or count a number of lines or colored zones. The number of lines or zones can be correlated with analyte concentration in the sample based on a calibration methodology. See, also, p. 31, lines 1 – 12.

The Boehringer reference only addresses quantitation of analyte concentration relative to a single device such as shown in the figures, e.g., FIG 2. This reference does not at all disclose, imply or suggest any methodology relating to the change in an analyte concentration level over time, e.g., based on obtaining samples from the same source on different occasions. As an example, the above-discussed needs to monitor hCG levels for purposes of assessing health of a pregnancy are not at all contemplated by the Boehringer reference.

THE REJECTION OF CLAIM 10 BASED ON THE BOEHRINGER REFERENCE IS IN ERROR.

Claim 10, a method for monitoring changes in an analyte level of a source requires the following combination wherein the claimed test units may correspond to a pair of units according to any one of the embodiments illustrated in FIGS 1 – 9:

"defining multiple measurably distinguishable sensitivity levels each indicative of a different amount of analyte in the source;

providing first and second test units,

the first test unit including a first region thereon responsive to the presence of analyte in the source at a first of the sensitivity levels,

the second test unit including a first region thereon responsive to the presence of analyte in the source at a second of the sensitivity levels;

providing a first sample from the source at a first time;

bringing the first sample into contact with the first unit to allow the first region thereon to provide an indication as to whether analyte is present in the sample at at least the first level;

providing a second sample from the source at a second time subsequent to providing the first sample; and

bringing the second sample into contact with the second unit to allow the first region thereon to provide an indication as to whether analyte is present in the second sample at at least the second level,

wherein indications of presence of analyte in the first sample and indications of presence of analyte in the second sample provide evidence as to whether there has been a change in analyte level between the first time and the second time."

In rejecting claim 10 the Examiner acknowledges that the Boehringer reference fails to teach that indications of presence of analyte in a first sample and indications of presence of analyte in a second sample provide evidence as to whether there has been a change in analyte level. However, this rejection is also premised on a conclusion that other features of claim 10 can be found in the Boehringer reference. As explained in the first appeal brief (as well as in the

response to the intial rejection based on Boehringer et al.) claim 10 was further distinguished, by way of an amendment filed on 14 July 2006. Claim 10 expressly specifies that the second sample is brought into contact with the second unit to indicate whether analyte is present "in the second sample" at at least the second level.

The final rejection of claim 10 (see page 6 of the second Final Office Action) urges that the claimed feature of

> "bringing the second sample into contact with the second unit to allow the first region thereon to indicate whether analyte is present in the second sample at at least the second level ..."

is found in the Boehringer reference. For this contention, the rejection incorrectly relies on a large number of citations in the Boehringer reference:

FIG 3; page 4, lines 22-38; page 5, lines 1 – 2; Page 6, lines 26 – 34; page 13, lines 27 – 37; page 14, lines 6 – 27; page 15, lines 29 – 32; page 23, lines 7 – 25; page 29, lines 35 – 38; page 30, lines 1 – 21; example 6 at page 48 and text under the heading "MULTIPLE LANE LATERAL FLOW TEST DEVICES" at pages 52 – 54.

These citations do little more than identify a device which might be suitable as a test unit to practice the claimed method and this certainly falls short of creating the above-quoted element of the claimed method. The rejection cites these numerous passages and examples from the Boehringer reference, but none of these, alone or in combination, teach or suggest

> "bringing the second sample into contact with the second unit to allow the first region thereon to indicate whether analyte is present in the second sample at at least the second level ..."

A second deficiency stems from the Examiner's acknowledgement that the Boehringer reference fails to teach that indications of presence of analyte in a first sample and indications of presence of analyte in a second sample provide evidence as to whether there has been a change in analyte level. However, the Toronto reference does not compensate for what the Boehringer reference lacks.

The second Final Office Action asserts (incorrectly) that the Toronto reference should be combined with the Boehringer reference, but the references are not consistent with one another. For example, the office action affirms that the test system of Toranto comprises a single device to test for analyte presence, but the single device of Toronto is not consistent with claim 10 nor consistent with the Boehringer reference. Claim 10 requires "multiple measurably distinguishable sensitivity levels" with the first region of the first test unit "responsive ... at a first of the sensitivity levels" and the first region of the second test unit "responsive to the presence of analyte in the source at a second of the sensitivity levels" but the Examiner has acknowledged that the delivery system of Toronto is a single device for testing the presence of an analyte. That is, the referenced "single devices" used in the delivery system are not shown to vary such that one device is responsive to a first sensitivity level and another device is responsive to a second sensitivity level. So, while the Toranto reference may suggest accessing test units on separate occasions, the disclosed test units do not have the requisite features.

Also, as already noted, the Boehringer reference fails to disclose "bringing the second sample into contact with the second unit" Based on the foregoing it appears that the Examiner is attempting to simply find pieces of the claimed invention and reassemble the invention from the prior art without requisite basis for doing so. It is one thing to merely combine references and quite another to break apart embodiments in order to reconstruct the claimed combination.

This reconstruction is a hindsight effort which is not sanctioned under the patent laws on obviousness unless there is a teaching to do so. The Examiner carries the burden of showing that one skilled in the art would modify the prior art by a piecemeal substitution. However, this burden cannot be carried when the very modifications are inconsistent with the teachings or intents of the reference. In this case, the delivery system embodiment of the Toranto reference is disclosed as comprising the device of Figure 1 therein and that device is suitable for the compact delivery system taught by Toronto et al. but not consistent with Appellant's teaching.

Paragraphs [0054] through [0057] of the Toranto reference refer to multiple assay test devices contained within a delivery system, wherein each single device is easy to use and, for example, determinative as to whether an analyte concentration is below a threshold. The devices in the delivery system are understood to be identical, and therefore responsive to the same threshold concentration of analyte. See, also, paragraph [0059].

It is also understood that for Toranto's embodiments of "delivery systems" the disclosed "test assay" device is "a simple strip containing a reactive site at one end, such that the reactive site provides a detection element in the presence of analyte ..." See paragraph [0066]. See also Figure 1 Such embodiments of assay test devices are known to be useful for rapid determination of alcohol detection. Paragraph [0146] indicates such a use by individuals in making decisions about whether or not to operate a motor vehicle.

Since the simple strips of Toronto provide all information needed each time an assay test is performed, there is no need to provide indications based on two different threshold levels to provide evidence as to whether there has been a change in analyte levels. Thus there is simply no motivation for reconstructing the delivery system of Toronto.

Nor is there motivation for modifying the Boehringer reference since that reference is not at all concerned with

> "bringing the second sample into contact with the second unit to allow the first region thereon to indicate whether analyte is present in the second sample at at least the second level ..."

or with

> "evidence as to whether there has been a change in analyte level between the first time and the second time."

That is, one skilled in the art would not have any motivation to modify either the Boehringer reference or the Toranto reference to meet the terms of claim 10. In fact, it is only the Appellant who teaches and recognizes the claimed subject matter.

In conclusion, the combination does not contain, and fails to suggest, Appellant's method of claim 10. Further, there is no description in any figures which would support the combination or the reconstruction of the prior art. Clearly, there is no disclosure in the Boehringer reference relating to the possibility of obtaining first and second samples from a given source wherein the second sample is obtained

> "on an occasion subsequent to providing the first sample ..."

The prior art does not contain the requisite elements and if it did, there would still be no motivation to reconstruct the embodiments disclosed therein in the absence of any motivation for doing so.

The second final office action presents argument to the contrary (see pages 6-7), but such argument has no merit and makes little sense. Merely recognizing that there are analytes which need to be monitored over time does not provide a basis for suddenly recognizing (in hindsight) how to revise two references in order to recreate that which is only taught by the Appellant.

It is only the applicant who teaches the concept of using multiple test units to assess temporal variations in analyte levels obtained from a source on different occasions.

It is also noted that, at best, Boehringer only discloses bringing the "same" sample from a source while Appellant teaches bringing different samples from a source on different occasions. Moreover, the rejection is contradictory in that the rejection under Section 103 expressly concedes that both references fail to teach the monitoring ... of temporal changes. Yet there is no ambiguity in the language of claims 10 and 20 which require providing samples on different occasions. It is not clear what distinction the Examiner wishes to make, but providing the samples on "different occasions" requires multiple events occurring at different times. Neither the Boehringer reference nor the Kenjyou reference suggest "subsequently bringing a different sample from the source into contact with a second of the test devices ..."

THE COMBINATION OF BOEHRINGER IN VIEW OF THE TORANTO REFERENCE TO REJECT CLAIM 10 IS DEFICIENT FOR AT LEAST FOUR REASONS

Based on the foregoing discussion it is clear that the combination is deficient for at least four reasons and cannot be used to reject claim 10. The rejection relies on at least three incorrect interpretations of the Boehringer reference and the embodiments used to form the combination are not consistent with one another or the claimed subject matter.

First, the Boehringer reference does not teach methods for monitoring changes in analyte levels in a sample source.

Second, the Boehringer reference does not teach "providing multiple test devices ..."

Third, the Boehringer reference does not teach "bringing a different sample from the source into contact with a second of the test devices."

Fourth, the Boehringer reference fails to teach the monitoring of temporal changes in analyte levels. This has been confirmed at page 12 in the first Final Office Action. While this admission is inconsistent with the rejections made of claim 10, the more significant concern with respect to rejection is that, in view of the above three incorrect interpretations of the primary reference (Boehringer), the Examiner's combination must be a hindsight and piecemeal reconstruction of the invention.

The combination results from a search among references for individual elements which can be re-assembled **as though** the claimed method is obvious. But absent the teachings of the Appellant, the claimed invention would not exist. This is because neither the Boehringer reference nor the Toranto reference are at all concerned with the problem addressed by the present invention. In fact, Toranto et al. teach away from the devices of the Boehringer reference. The Toranto reference teaches that it is desirable to store multiple assay tests which are single assay devices (not of the type having a plurality of regions each responsive at a different sensitivity level) because the single assay devices of Toranto et al. are small, easy to use, suitable for flexible use and storable in the delivery systems of FIGS 3 and 4. See Pars [0055] and [0056].

None of the embodiments of the Toranto delivery system are consistent with the devices according to claim 10 or consistent with the devices of the Boehringer reference because Toranto teaches, with reference to FIGS 3 and 4, a compartment 44 that holds "multiple assay tests ..." wherein individuals may use more than one test on a given occasion to determine whether their analyte concentration has dropped. This flexibilty is inconsistent with the Boehringer reference.

Applicant claims a method which defines "multiple measurably distinguishable sensitivity levels each indicative of a different amount of analyte in the source" and each device includes a region responsive to a different one of the sensitivity levels.

The Toranto reference teaches away from such a test unit. Instead of desiring devices each including a region responsive to a different one of the sensitivity levels, the Toranto reference only teaches individual assay tests that are small and suitable for flexible use in combination with a storage delivery system. See, again, Pars [0055] and [0056]. Therefore the Toranto reference should not be combined with the Boehringer reference. Toranto et al

recognizes a different need, inconsistent with the Boehringer reference.:

> "because individuals may use more than one [test] on a given occasion, for example, to determine if their analyte concentration has dropped over time, the delivery system stores multiple assay tests." See Par. [0059].

For these reasons, Toranto et al. would have no motivation to employ the devices of the Boehringer reference in the delivery system of Toranto et al. For all of the above reasons the rejection of claim 10 is in error and must be reversed.

7B(2) THE REJECTION OF CLAIMS 11 – 16, 19 AND 28 WHICH EACH DEPEND FROM CLAIM 10, BASED ON THE BOEHRINGER REFERENCE IN VIEW OF THE TORANTO REFERENCE, IS IN ERROR.

Each of the claims depending from claims 10 and 20 and rejected under section 102 defines distinct and non-obvious subject matter and further distinguishes the invention over the prior art.

CLAIM 11 FURTHER DISTINGUISHES OVER THE ART OF RECORD

Claim 11, which depends from claim 10 further distinguishes over the Boehringer reference, requiring, among other features, that the first unit includes a second region responsive to presence of the second level of analyte and the step of bringing the first sample into contact with the first unit includes allowing said second region to indicate whether analyte is present in the sample at at least the second level. These features provide another novel combination.

CLAIM 12 FURTHER DISTINGUISHES OVER THE ART OF RECORD

Claim 12, which depends from claim 10 further distinguishes over the Boehringer reference, requiring, among other features, that the first unit includes a second region responsive

to presence of one measurably distinguishable sensitivity level different than the first of the sensitivity levels and the step of bringing the first sample into contact with the first unit includes allowing said second region to indicate whether analyte is present in the sample at at least said one sensitivity level different than the first of the sensitivity levels. These features also provide another novel combination.

CLAIM 13 FURTHER DISTINGUISHES OVER THE ART OF RECORD

Claim 13, which depends from claim 12 further distinguishes over the Boehringer reference, requiring, among other features, that said one measurably distinguishable sensitivity level different than the first of the sensitivity levels is substantially the same as the second of the sensitivity levels. This feature also provides another novel combination.

CLAIM 14 FURTHER DISTINGUISHES OVER THE ART OF RECORD

Claim 14, which depends from claim 10 requires that the second test unit includes a second region thereon responsive to the presence of analyte in the source at the first of the sensitivity levels. This feature also provides another novel combination.

CLAIM 15 FURTHER DISTINGUISHES OVER THE ART OF RECORD

Claim 15, which depends from claim 10 requires that the step of providing the first test unit includes forming thereon at least three regions each responsive to the presence of analyte in the source at a different one of the multiple measurably distinguishable sensitivity levels. This feature also provides another novel combination.

CLAIM 16 FURTHER DISTINGUISHES OVER THE ART OF RECORD

Claim 16, which depends from claim 15 requires that the step of providing the second test unit includes forming thereon at least three regions each responsive to the presence of analyte in

the source at a different one of the multiple measurably distinguishable sensitivity levels. This feature also provides another novel combination.

CLAIM 19 FURTHER DISTINGUISHES OVER THE ART OF RECORD

Claim 19, which depends from claim 10 requires that the step of defining multiple measurably distinguishable sensitivity levels each indicative of a different amount of analyte in the source is accomplished by forming at least the first regions. This feature also provides another novel combination.

CLAIM 28 FURTHER DISTINGUISHES OVER THE ART OF RECORD

Claim 28, which depends from claim 10 requires that the step of providing the first and second test units includes forming the first and second units separate and apart from one another. The claimed combination is not taught or suggested.

7B(3) THE REJECTION OF CLAIMS 17 AND 18 WHICH EACH DEPEND FROM CLAIM 16, BASED ON THE BOEHRINGER REFERENCE IN VIEW OF THE TORANTO REFERENCE, AND IN FURTHER VIEW OF COLE IS IN ERROR.

7B(3)i THE REJECTION OF CLAIM 17 UNDER SECTION 103 IS IMPROPER.

This rejection of claim 17 is improper for reasons in addition to the reasons presented for allowability of claims 10, 15 and 16 from which it depends.

Claim 17 requires that:

> "the steps of providing the first and second test units are performed such that at least one of the three regions of the first unit and one of the three regions of the second unit are responsive to the presence of analyte in the source at substantially the same sensitivity level."

The rejection based on the Boehringer reference in view of Toranto and in further view of Cole, relies upon the Cole reference to show one of three regions responsive to "substantially the same sensitivity level" but the Cole reference does not teach or suggest use of multiple devices and therefore the combination does not resuilt in the invention of claim 17. Further, it is believed that the combination required to meet the terms of these claims is a piecemeal and hindsight reconstruction of the prior art in the absence of any motivation to perform such a reconstruction.

7B(3)ii THE REJECTION OF CLAIM 18 UNDER SECTION 103 IS IMPROPER.

Claim 18 was also rejected over the Boehringer reference in view of Toranto and in further in view of Cole. This rejection of claim 18 is improper for reasons in addition to the reasons presented for allowability of claims 10, 15 and 16 from which it depends.

Claim 18 requires that:

> "each of the regions of the first unit is responsive to substantially the same level of analyte as one of the regions of the second unit."

The rejection ofclaim 18 relies upon the Cole reference to show that each of the regions of the first unit is responsive to substantially the same level of analyte as one of the regions of the second unit, but the Cole reference does not teach or suggest use of multiple devices and therefore the combination does not result in the invention of claim 18. Further, it is believed that the combination required to meet the terms of these claims is also a piecemeal and hindsight reconstruction of the prior art. Absent the Appellant's techings, there is no motivation to perform such a reconstruction.

7B(4) THE REJECTION OF CLAIMS 26 AND 27 WHICH EACH DEPEND FROM CLAIM 25, UNDER 35 U.S.C. SECTION 103(A) AS BEING UNPATENTABLE OVER TORANTO ET AL. (US 2003/0175992) IN VIEW OF O'CONNOR ET AL. (US 2003/0124737) IS IN ERROR.

7B(4)i THE REJECTION OF THE DEPENDENT CLAIM 26 UNDER SECTION 103 IS LACKS ADEQUATE SUPPORT.

Claim 26, which depends from claim 25 is allowable because the rejection of claim 25 under Section 102 is in error. Furthermore, claim 26 further distinguishes over the combination of Toranto in view of O'Connor by requiring that the second occasion is at least one day after the

first occasion. The rejection asserts that it would have been obvious to include with the method of Toranto a change in concentration of chorionic gonadotrophin as the analyte, because O'Connor recognizes importance of measuring hCG over time. However, the devices used in the delivery system of Toranto are not capable of providing this information and the Examiner has failed to address this deficiency. Reversal of the rejection is requested.

7B(4)ii THE REJECTION OF THE DEPENDENT CLAIM 27 UNDER SECTION 103 LACKS ADEQUATE SUPPORT.

Claim 27, which also depends from claim 25, is allowable because the rejection of claim 25 under Section 102 is in error. Furthermore, claim 27 further distinguishes over the combination of Toranto in view of O'Connor by requiring that the second occasion is at least 72 hours after the first occasion. The rejection asserts that it would have been obvious to include with the method of Toranto a change in concentration of chorionic gonadotrophin as the analyte, because O'Connor recognizes importance of measuring hCG over time. However, the devices used in the delivery system of Toranto are not capable of providing this information and the Examiner has failed to address this deficiency. Reversal of the rejection is requested.

7C. ALL OF THE CLAIMS SHOULD BE PASSED TO ISSUANCE.

Based on the foregoing, the Final Rejection as applied to every one of the claims is in error. Every one of the claims stands up to all of the art of record. Reversal is therefore requested so the claims may be passed to issuance.

8. APPENDICES

An appendix containing a copy of the claims involved in this appeal is provided herewith. No evidence appendix or related proceedings appendix is provided because no such evidence or related proceeding is applicable to this appeal.

Respectfully submitted,

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9. APPENDIX OF CLAIMS ON APPEAL

1. A method for determining, between two times, a change in a level of concentration of an analyte present in a source, comprising:

providing multiple unitary test devices, each unitary test device including a plurality of regions, each region responsive at a different sensitivity level to indicate presence of the analyte in the source;

bringing a first sample from the source into contact with a first of the unitary test devices at a first time to induce, at the first time, a visually observable response in one or more regions of the first test device based on the source containing a minimum level of analyte concentration; and

subsequently bringing a second and different sample from the same source into contact with a second of the unitary test devices at a second time to induce at the second time, a visually observable response in one or more regions of the second test device based on the source containing a minimum level of analyte concentration; and

comparing a visually observable response induced in the first test device at the first time directly with a visually observable response induced in the second test device at the second time to provide information about a change in the level of analyte concentration between the two times.

10. A method for monitoring changes in analyte level of a source, comprising:

defining multiple measurably distinguishable sensitivity levels each indicative of a different amount of analyte in the source;

providing first and second test units,

the first test unit including a first region thereon responsive to the presence of analyte in the source at a first of the sensitivity levels,

the second test unit including a first region thereon responsive to the presence of analyte in the source at a second of the sensitivity levels;

providing a first sample from the source at a first time;

bringing the first sample into contact with the first unit to allow the first region thereon to provide an indication as to whether analyte is present in the sample at at least the first level;

providing a second sample from the source at a second time subsequent to providing the first sample; and

bringing the second sample into contact with the second unit to allow the first region thereon to provide an indication as to whether analyte is present in the second sample at at least the second level,

wherein indications of presence of analyte in the first sample and indications of presence of analyte in the second sample provide evidence as to whether there has been a change in analyte level between the first time and the second time.

11. The method of claim 10 wherein the first unit includes a second region responsive to presence of the second level of analyte and the step of bringing the first sample into contact with the first unit includes allowing said second region to indicate whether analyte is present in the sample at at least the second level.

12. The method of claim 10 wherein the first unit includes a second region responsive to presence of one measurably distinguishable sensitivity level different than the first of the sensitivity levels and the step of bringing the first sample into contact with the first unit includes allowing said second region to indicate whether analyte is present in the sample at at least said one sensitivity level different than the first of the sensitivity levels.

13. The method of claim 12 wherein said one measurably distinguishable sensitivity level different than the first of the sensitivity levels is substantially the same as the second of the sensitivity levels.

14. The method of claim 10 wherein the second test unit includes a second region thereon responsive to the presence of analyte in the source at the first of the sensitivity levels.

15. The method of claim 10 wherein the step of providing the first test unit includes forming thereon at least three regions each responsive to the presence of analyte in the source at a different one of the multiple measurably distinguishable sensitivity levels.

16. The method of claim 15 wherein the step of providing the second test unit includes forming thereon at least three regions each responsive to the presence of analyte in the source at a different one of the multiple measurably distinguishable sensitivity levels.

17. The method of claim 16 wherein the steps of providing the first and second test units are performed such that at least one of the three regions of the first unit and one of the three regions of the second unit are responsive to the presence of analyte in the source at substantially the same sensitivity level.

18. The method of claim 16 wherein each of the regions of the first unit is responsive to substantially the same level of analyte as one of the regions of the second unit.

19. The method of claim 10 wherein the step of defining multiple measurably distinguishable sensitivity levels each indicative of a different amount of analyte in the source is accomplished by forming at least the first regions.

20. A method for monitoring changes in analyte level of a source, comprising:

providing two or more test units each including multiple regions thereon, each region in each unit responsive to the presence of an analyte in the source at a sensitivity level measurably distinguishable from another region in the same test unit;

bringing a first sample from the source into contact with a first of the units to allow one or more of the regions thereon to indicate whether the analyte is present in the sample at at least one of the levels; and

on an occasion subsequent to providing the first sample, bringing a second sample from the source into contact with a second of the units to allow one or more of the regions thereon to indicate whether the analyte is present in the second sample at at least one of the levels,

wherein different indications of presence of analyte in the first and second samples provide evidence as to whether there has been a change in analyte level subsequent to providing the first sample.

21. The method of claim 20 wherein the step of providing one of the test units includes adhesively mounting the multiple regions on a substrate.

25. A method for determining a change in a level of concentration of an analyte present in a source, comprising:

providing multiple unitary test devices, each unitary test device including a plurality of regions, each region responsive at a different sensitivity level to indicate presence of the analyte in the source without being determinative of a numerical concentration of the analyte in the source;

on a first occasion, bringing a sample from the source into contact with a first of the unitary test devices to induce a visually observable response thereto in one or more regions of the first test device when the source contains a predetermined minimum level of analyte concentration;

subsequently, on a second occasion, bringing a different sample from the same source into contact with a second of the unitary test devices to induce a visually observable response thereto in one or more regions of the second unitary test device when the source contains a predetermined minimum level of analyte concentration; and

comparing a visually observable response induced in the first test device directly with a visually observable response induced in the second test device to provide information about a change in the level of analyte concentration without requiring determination of analyte concentration in the source on either occasion.

26. The method of claim 25 wherein the first and second test devices are configured to indicate presence of chorionic gonadotrophin as the analyte, and wherein the second occasion is at least one day after the first occasion, the method indicating whether analyte concentration has increased between the first and second occasions.

27. The method of claim 25 wherein the first and second test devices are configured to indicate presence of chorionic gonadotrophin as the analyte, and wherein the second occasion is at least 72 hours after the first occasion, the method indicating whether analyte concentration has doubled between the first and second occasions.

28. The method of claim 10 wherein the step of providing the first and second test units includes forming the first and second units separate and apart from one another.

29. The method of claim 20 wherein the step of providing two or more test units includes forming the test units separate and apart from one another.

10. EVIDENCE APPENDIX - 37 CFR 41.37(c) (1) (ix)

None

11. RELATED PROCEEDINGS APPENDIX - 37 CFR 41.37(c) (1) (x)

None